REMARKS

This is in response to the Office Action dated March 27, 2008. Applicants have carefully reviewed and considered the Office Action mailed on Mar 27, 2008, and documents cited therewith.

Claims 72-90, 93, 96, 97 and 99-101 were examined. Claim 72, 73, 76, 82, 96 and 97 are amended. Claim 77-81, 84-90, 93, 99 are cancelled and Claims 100 and 101 are withdrawn. Support for the amendment can be found in the present application. Accordingly, no question of new matter should arise, and entry of this amendment is respectfully requested.

Reconsideration and withdrawal of the rejections of the claims, in view of amendments and remarks presented herein, is respectfully requested.

In the Office Action mailed on March 27, 2008, the Examiner has withdrawn Claim 100 and 101 from consideration and rejected Claims 72-90, 93, 96, 97, and 99 under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement.

In the same Office Action , the Examiner has rejected Claims 72-79, 84, 87, 93 and 96-99 under 35 U.S.C. 102 (b) as being anticipated by Jain ("Controlled drug delivery from a novel injectable *in situ* formed biodegradable PLGA microsphere system," Dissertation, University of Rhode Island, 1998, abstract, cited in applicant's specification; full document submitted by applicant on 9/11/07); claims 72-79, 84, 87-90, 93 and 96-99 under 35 U.S.C. 102(a) as being anticipated by Jain et al. ("Comparison of Various Injectable Protein-Loaded Biodegradable Polu(Lactide-co-glycolide) (PLGA) devices: In situ-formed implant versus In-Situ Formed Microspheres Versus Isolated Microspheres" in Pharmaceutical Development and Technology, 5(2), 201-207 (2000)), and rejected Claims

72-80, 82, 84, 87, 93 and 96-98 under 35 U.S.C 102(a) as being anticipated by Jain "The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490 and claims 81, 85, 86 and 88-90as being obvious in view of this reference. .

The applicants submit the amendments and following remarks to address the Examiner's objections and rejections

Matters raised by the Examiner on pages 2 and 3 of the Office Action dated March 27, 2008.

Applicants withdraw, with traverse, the Claims 100 and 101. The withdrawn claims have not been cancelled in order to reserve the right to pursue the subject matter in subsequent applications. Accordingly, applicants respectfully request favorable consideration of the present application.

The 35 U.S.C. 112 Rejection/New Matter

The Examiner rejected Claims 72-90, 93 and 96-99 under 35 U.S.C 112, first paragraph, as failing to comply with the written description requirement.

Claim 72 has been amended. This claim now contains the term "or inactive agent" as per suggestions of examiner himself in recent office action dated Mar 27, 2008, where Examiner mentioned that previously amended Claim 72 excludes the biologically inactive agent from the composition. Support for this can be found in abstract, paragraphs [0008], [0012], [0014], [0015] and [0016] in the specifications.

Therefore, in light of amended claim, there is no new matter addition and hence applicants respectfully request that this new matter rejection be withdrawn.

Claims 72-90, 93, and 96, 97 and 99 are rejected under 35 U.S.C 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The Examiner pointed towards the ambiguity how the discontinuous phase contains both biologically active agent and polymer both. Applicants draw the attention of the Examiner towards the fact that composition of the invention is gelled polymeric dispersion system in which there are two phases, continuous phase and discontinuous phase. The continuous phase comprises an oily phase and the discontinuous phase consists of polymer dissolved in water soluble organic solvent in which drug which is to encapsulated is also dissolved or dispersed so that when this dispersion comes in contact with body fluids it forms microparticles containing drug entrapped in it. Hence, the discontinuous phase comprises both polymer and drug. This is also supported in Paragraph 79 where it is stated that , "...bioactive agent is added to polymer solution prior to emulsification and drug can be added as solution or suspension]

Claims 77 to 81 and 84-90 have been cancelled. Claim 93 has also been cancelled; hence the rejection with respect to these claims is moot.

The Examiner mentions that Claim 97 as presented contradicts the concept of the claimed delivery system of Claim 72. As explained earlier also, the "aqueous medium" as mentioned in Claim 97 refers to aqueous medium present within, in or on the body i.e body fluids and is not referring to aqueous medium or water in the delivery system as such. To make this concept clearer, Claim 97 has been amended to add word "present inside a body". This is "a body" rather than "the body" to provide antecedent basis. As, it is clear that the delivery system of the present invention is an in situ delivery system, wherein the microparticles are formed *in situ*, when the discontinuous phase comes in contact with

aqueous medium i.e. aqueous fluid present inside the body. Claim 73 is also being amended to include the phrase "present inside a body."

Claim 99 has been cancelled, so the rejection with respect to Claim 99 is rendered moot.

In view of the above, Claims 72-76, 82-83, and 96-97 comply with the written description requirement. Applicants respectfully request that this rejection under 35 U.S.C 112, second paragraph be withdrawn.

The 35 U.S.C 102 Rejections

The Examiner rejected Claims 72-79, 84, 87, 93 and 96-99 under 35 U.S.C 102 (b) as being anticipated by Jain ("Controlled drug delivery from a novel injectable in situ formed biodegradable PLGA microsphere system," Dissertation, University of Rhode Island, 1998, abstract, cited in applicant's specification). Applicants respectfully traverse this rejection.

Examiner said that PEG meeting Claim 76 is present, so PEG has been deleted from the Claim 76, to comply with Examiner's requirements. Further, Examiner said that Tween meeting the requirements for surfactant/emulsifier in Claims 72 and 98 is present. Claim 72 has been amended to delete the term "emulsifier" to comply with Examiner's requirements.

Claim 98 wascancelled in the response to the Office Action dated June 7, 2007, hence the rejection with respect to Claim 98 is already rendered moot. Claims 77-79, 84, 87, 93, 99 have been cancelled so rejection with respect to Claim 77-79, 84, 87, 93, 99 is rendered moot.

Therefore, Claims 72-76, 82-83, 96-97 are not anticipated by Jain and it is respectfully requested that rejection under 35 U.S.C 102 (b) be withdrawn.

The Examiner rejected Claims 72-79, 84, 87, 93 and 96-99 under 35 U.S.C 102 (a) as being anticipated by Jain et al. ["Comparison of various injectable protein loaded biodegradable poly (lactide-co-glycolide) PLGA devices: In situ formed implant versus in situ formed microspheres versus isolated microspheres", in Pharmaceutical Development and Technology, 5(2), 201-207 (2000)].

Examiner said that PEG meeting Claim 76 is present, so PEG has been deleted from the Claim 76, to comply with Examiner's requirements. Further, examiner said that Tween meeting the requirements for surfactant/emulsifier in Claims 72 and 98 is present. Claim 72 has been amended to delete the term "emulsifier" to comply with Examiner's requirements. As stated above, Claim 98 has already been cancelled. Thus the rejection with respect to Claim 98 is already rendered moot. Claims 77-79, 84, 87, 93, 99 have been cancelled so rejection with respect to Claim 77-79, 84, 87, 93, 99 is rendered moot.

Therefore, Claims 72-76, 82-83, and 96-97 are not anticipated by Jain and it is respectfully requested that rejection under 35 U.S.C 102 (b) be withdrawn.

The Examiner rejected Claims 72-80, 82, 84, 87, 93 and 96-99 under 35 U.S.C 102 (a) as being anticipated by Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490].

For the reasons explained above, claims 72-76, and 96-98 are not anticipated by this reference. Claims 77-80, 84, 87, 93, and 99 have been cancelled so the rejection with respect to Claim 77-77-80, 84, 87, 93, and 99 is rendered moot. Examiner said that vaccine of

Jain meets Claim 82, so accordingly, Claim 82 has been amended to delete the term "vaccine" from the claim.

Therefore, Claims 72-76, 82-83, 96-97 are not anticipated by Jain and it is respectfully requested that rejection under 35 U.S.C 102 (b) be withdrawn.

The 35 U.S.C. 103 Rejection

The Examiner rejected Claims 81 and 85 under 35 U.S.C 103 (a) as being unpatentable over Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490].

Claims 81 and 85 are cancelled; hence rejection with respect to Claim 81 and 85 is rendered moot.

The Examiner rejected Claim 86 under 35 U.S.C. 103 (a) as being unpatentable over Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490].

Claim 86 is cancelled; hence rejection with respect to Claim 86 is rendered moot.

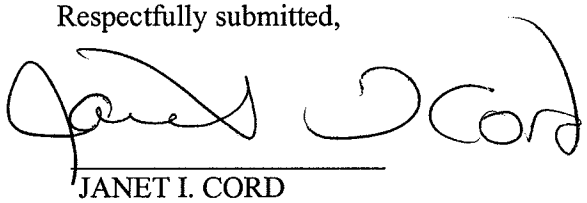
The Examiner rejected Claims 88-90 under 35 U.S.C. 102 (a) as anticipated by or, in the alternative under 35 U.S.C. 103 (a) as obvious over Jain ["The manufacturing techniques of various drug loaded biodegradable poly (lactide-co-glycolide) PLGA devices" in Biomaterials, 21, (2000), 2475-2490].

Claims 88-90 are cancelled; hence rejection with respect to claim 88-90 is rendered moot.

Conclusion

Applicants respectfully submit that the amended claims and patent application is in condition for allowance and notification to that effect is earnestly requested. If desired, the Examiner is invited to conduct a telephone conference to expedite the prosecution of the subject application. In such a case, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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